

## *The Sunlamp ANPRM -Summary of Comments and Data*

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## *Objectives*

- Explain the process of rulemaking
- why did we publish the ANPRM ?
- Did we get answers to our concerns ?
- Is data sufficient for us to publish a proposed rule?

## *Why did we publish the ANPRM*

- Reports of a melanoma "epidemic"
- Reports of a melanoma-sunlamp link
- Report of an action spectrum showing that UVA was more efficient in producing melanoma than in producing erythema
- All caused great concern in scientific/medical community

## *The "process" of rulemaking*

- Advanced Notice of Proposed Rulemaking ( ANPRM )
- Proposed Rule
- Final Rule
  - scientific evaluation
  - advice from TEPRSSC
  - address responses to Proposed Rule

## *Response to the ANPRM*

- 27 submissions
  - indoor tanning industry (4)
  - lamp manufacturers (8)
  - dermatology organizations (2)
  - academia (3)
  - salon owners (4)
  - State and County regulatory agencies (5)
  - Insurance company (1)

## *Biological basis for standards*

- Agreement that Phototype I should not get exposed to UV
- Disagree on Phototype II
  - dermatologists - phototype II can burn easily
  - indoor tanning industry - phototype II can tan, but must be careful - 2 subtypes
- Agreement that all should avoid "burning" doses

### *Biological Basis for Standards 2*

- Agreement that tanning is photoprotective
  - disagreement over degree of protection
- Major disagreements over other “benefits” from “tanning” doses
  - role of vitamin D is important
  - dosage need to produce adequate vitamin D is major consideration

### *Exposures schedules*

- Did not get any exposure schedule based on skin cancer risks
- should be expanded to other phototypes
- Got new data on current FDA exposure schedule
  - does not lead to burns
  - individuals don't tan until 6 - 8 session

### *Training*

- No disagreement – all emphasized importance of training
  - Important to inform customers, particularly about drug interactions – C26-Amy Leslie
  - A trained operator should cover the topics in FDA's warning label with first-time tanners C17-ST
  - Salons are an excellent place for educational materials, can take them home – C15-DS

### *Melanoma warning*

- melanoma-sunlamp link lacks rigorous scientific proof ( ANPRM comments, meetings, recent reviews )
- some studies show positive association, others negative, and others no association
- Only one disagreement with proposal to require warning statements in catalogs, specification sheets, and brochures

### *Informed Consent*

- Agreement on value of informed consent statements
- Efforts underway by indoor tanning industry to require written consent statements for young clients

### *Other comments*

- Timers - separate the timer from the emergency shut-off switch
- Eyewear - “if you see light, change eye protection”
- make requirements for sanitary pillows

### *Efficacy ratings for bulbs*

- Agreement that a rating system is needed
- Suggestion that the UV index be used as part of the rating system
- Disagreement as to whether only testing of lamps is needed, or testing of whole sunlamp systems ( booths ) ( beds )

### *Re-certification*

- Anyone who changes specification of lamps becomes a manufacturer
- Many comments that this requirement be strong. Concerns about insurance coverage

### *No plans to ban sunlamps*

- the melanoma-sunlamp connection is not well established
- individual choice
- risks are fairly well understood by public

### *Three ways to deal with "melanoma" warning*

- A specific melanoma warning - err on the side of public health
- No specific melanoma warning - data is inconclusive
- IEC warning -
  - skin cancer ( sometimes fatal )

### *The future*

- Continue to evaluate data and comments from the ANPRM
- Work with those who responded to ANPRM - clarifications and additional data
- FDA and industry - work with consensus standards organizations, e.g., IEC

### *The future 2*

- monitor current research, including CDRH studies
- Brief indoor tanning industry - Nov/Chicago
- Draft proposed rules after full evaluation
- brief TEPRSSC
- publish proposed rule